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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,599	02/01/2001	Kenneth F. Buechler	071949-2404	9314

7590

07/05/2002

Michael A. Whittaker
FOLEY & LARDNER
23rd Floor
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San Diego, CA 92101

EXAMINER

BAKER, MAURIE GARCIA

ART UNIT

PAPER NUMBER


1627

DATE MAILED: 07/05/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/776,599	Applicant(s) Buechler et al	
Examiner Maurie Garcia Baker, Ph. D.	Art Unit 1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-29 are subject to restriction and/or election requirement

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Jyothsna Venkat, Supervisory Patent Examiner, at (703) 308-2439. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-22, drawn to a water soluble hybrid phthalocyanine derivative, classified variously, for example, class 540, subclass 128.
 - II. Claims 23-27, drawn to a conjugate, classified variously, for example, class 424, subclass 193.1.
 - III. Claim 28, drawn to a competitive method of assay (using a ligand analogue coupled to a signal development element), classified variously, for example, class 435, subclass 7.93.
 - IV. Claim 29, drawn to a **non**-competitive method of assay (using a receptor coupled to a signal development element), classified variously, for example, class 436, subclass 501.
2. The inventions are distinct, each from the other because of the following reasons:
3. Groups I and II represent separate and distinct products. They differ in respect to their properties, their use and the synthetic methodology for making them. Therefore, they have different issues regarding patentability and enablement and represent patentably distinct subject matter. In the instant case, the water soluble hybrid

phthalocyanine derivative is a single compound, while the conjugate comprises a “sulfonated hybrid phthalocyanine derivative” *and* a specific “substituent”. Compounds and conjugates also have different uses and require different methods of making.

4. Group I and Groups III and IV are related as product and process(es) of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the water soluble hybrid phthalocyanine derivative could be used in a materially different process of using such as a label(tag) for compounds in a combinatorial synthesis scheme.

5. Groups III and IV are different methods. The methods are different because they use different steps, require different reagents and will produce different products and/or results. They therefore have different issues regarding patentability and enablement and represent patentably distinct subject matter. In the instant case, the method of Group III is a competitive method, while the method of Group IV is not (different steps). Also, the methods use completely different reagents. Group III requires a *ligand analogue* coupled to a signal development element, while Group IV requires a *receptor* coupled to a signal development element.

6. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different inventions would

require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

7. This application contains claims directed to patentably distinct species of the claimed invention for **Groups I and II**. Election is required as follows.

8. If applicant elects the invention of **Group I**, applicant is required to elect from the following patentably distinct species. Claim 1 is generic.

Species of water soluble hybrid phthalocyanine derivative

A *specific* compound should be elected, with all portions thereof defined. All atoms and bonds of the compound should be specifically shown. That is, one of the derivatives shown in claims 2-22 should be elected.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

9. If applicant elects the invention of **Group II**, applicant is required to elect from the following patentably distinct species. Claim 23 is generic.

Species of conjugate

A *specific* conjugate should be elected, with all portions defined. The election should result in the selection of a specific "sulfonated hybrid phthalocyanine derivative" and a specific "substituent".

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting

materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

10. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

11. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and ***a listing of all claims readable thereon***, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

12. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

13. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the

prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


16. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is

(703) 308-0065. The examiner can normally be reached on Monday-Thursday from 8:30 to 6:00 and alternate Fridays.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached on (703) 308-2439. The fax phone number or the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
June 27, 2002


MAURIE E. GARCIA, PH.D.
PATENT EXAMINER



RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

FIRM:

PAGES, INCLUDING COVERSHEET:

PHONE NUMBER:

TO EXAMINER: Maurie Garcia Baker, Ph.D.

ART UNIT: 1627

SERIAL NUMBER:

FAX/TELECOPIER NUMBER: (703) 308-4315

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COMMENTS: _____

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